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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/696,749	10/24/2000	CLAUDIA B. JAFFE	01-050210US	2329

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EXAMINER

BROWN, JENNINE M

ART UNIT	PAPER NUMBER
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1755

DATE MAILED: 01/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/696,749

Applicant(s)

JAFJE, CLAUDIA B.

Examiner

Jennine M. Brown

Art Unit

1755

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

Claims Analysis

The "electroosmotic pump" terminology based on Applicants arguments and as defined in the specification is not a separate pump unit or mechanical pumping mechanism installed in the substrate but the pressure created from using electroosmotic movement of fluid in one of the channels which subsequently causes pressure in the adjoining channels and is generally electrode driven.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1-9 and 16-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Taylor, et al. (US 6375817).

Taylor et al. teach a microfluidic device having a plurality of channels (Figure 4; col. 4, l. 5-9; col. 8, l. 40-42) a deep channel and a shallow channel with cross sectional areas (col. 2, l. 66-67; col. 5, l. 2-15) having a pressure source in fluid communication with the channel (col. 5, l. 16-50) to introduce one or more samples (col. 4, l. 36-63) and an electrokinetic controller to transport one or more samples through the separation channel by voltage (col. 3, l. 10-15). The channel depth ranges from 0.1 μm to 1000 μm (col. 8, l. 40-47) and the channel widths range from 10 μm to 100 μm (col. 8, l. 40-47). The separation channel has a separation matrix comprising agarose or polyacrylamide gel (col. 5, l. 42-44; col. 7, l. 11-18). The pressure

source can be positive pressure (col. 5, l. 18-20) or negative pressure otherwise known as vacuum (col. 6, l. 61-67). One pressure source is an electroosmotic pump. Buffer or salt is used in the channels (col. 3, l. 2-3, 9). Plug injection is used to move the injected sample from the injection channel to the separation channel (col. 2, l. 23-58).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor, et al. (US 6375817) as applied to claims 1-9, 16-24 above, and further in view of Christel, et al. (US 6368871).

Taylor, et al. teach a microfluidic device as described previously. Taylor, et al. do not specify the ratio of depth to width. Christel, et al. teach the depth to width ration is 2:1, 10:1 or more preferably 20:1 (col. 2, l. 49-55; col. 7, l. 44-47; col. 12, l. 60-61).

It would have been obvious to one of ordinary skill in the art to modify the apparatus of Taylor, et al. to use the modified depths because the increased surface area is ideal for mixing

of fluids because mixing by diffusion can be very slow and the er the channel, the greater surface area which should decrease the length necessary to mix in the channels, making the devices more compact and less expensive to manufacture.

Response to Arguments

1. In response to the 102(e) arguments regarding Taylor, et al. (US 6375817), the examiner points out the appropriate section in the MPEP for maintaining the anticipation rejection according to section 715:

"SITUATIONS WHERE 37 CFR 1.131 AFFIDAVITS OR DECLARATIONS ARE INAPPROPRIATE

An affidavit or declaration under 37 CFR 1.131 is not appropriate in the following situations:

(B) Where the reference U.S. patent or U.S. patent application publication claims the same patentable invention. See MPEP § 715.05 for a discussion of "same patentable invention" and MPEP § 2306. Where the reference patent and the application or patent under reexamination are commonly owned, and the inventions defined by the claims in the application or patent under reexamination and by the claims in the patent are not identical but are not patentably distinct, a terminal disclaimer and an affidavit or declaration under 37 CFR 1.130 may be used to overcome a rejection under 35 U.S.C. 103. See MPEP § 718." Since the applications are not commonly owned, a declaration under 37 CFR 1.130 is also not appropriate. Referring now to MPEP 715.05,

"U.S. Patent or Application Publication Claiming Same Invention

When the reference in question is a noncommonly owned U.S. patent or patent application publication claiming the same invention as applicant and its publication date is less

than 1 year prior to the presentation of claims to that invention in the application being examined, applicant's remedy, if any, *must be by way of 37 CFR 1.608 instead of 37 CFR 1.131*. If the reference is claiming the same invention as the application and its publication date is less than 1 year prior to the presentation of claims to that invention in the application, this fact should be noted in the Office action. The reference can then be overcome only by way of interference. See MPEP § 2306-2308. If the reference is claiming the same invention as the application and its publication date is 1 year or more prior to the presentation of claims to that invention in the application, a rejection of the claims of the application under 35 U.S.C. 135(b) should be made. See *In re McGrew*, 120 F.3d 1236, 1238, 43 USPQ2d 1632, 1635 (Fed. Cir. 1997) (The court holding that application of 35 U.S.C. 135(b) is not limited to inter partes interference proceedings, but may be used as a basis for ex parte rejections.)" The reference is claiming the same invention as the application but the publication date is more than 1 year prior to the presentation of claims to that invention in the application. The examiner has also referred to MPEP 2306,

"2308.01 Patent Has Filing Date Earlier Than Application

...

If the effective filing date of the application is more than 3 months after the effective filing date of the patent, 37 CFR 1.608(b) requires that the applicant must file (A) evidence, such as patents, publications and other documents, and one or more affidavits or declarations which demonstrate that applicant is prima facie entitled to a judgment relative to the patentee, and (B) an explanation stating with particularity the basis upon which the applicant is prima facie entitled to the judgment. *If an applicant is claiming the same invention as a patent which has an earlier effective United States filing date but there is not a statutory bar against the*

application, and the applicant has not submitted the items required by 37 CFR 1.608(a) or (b), as appropriate, the application should be rejected under 35 U.S.C. 102(e)/103. A statement should be included in the rejection that the patent cannot be overcome by an affidavit or declaration under 37 CFR 1.131 but only through interference proceedings. Note, however, 35 U.S.C. 135(b) and MPEP § 2307. The applicant should also be advised that an affidavit under 37 CFR 1.608(b) or evidence and an explanation under 37 CFR 1.608(b), as appropriate, must be submitted and it should be stated, if applicable, that the patentee has been accorded the benefit of an earlier U.S. application.

If the applicant does not agree he or she is claiming the same invention as the patent, and files an affidavit under 37 CFR 1.131, the rejection should be repeated and made final. The rejection should specify what the count or counts of the interference between the application and the patent would be. If the applicant still disagrees with the examiner, the rejection may be appealed to the Board of Patent Appeals and Interferences, and the question of whether the application and the reference patent are claiming the same invention may be argued on appeal, inasmuch as the 37 CFR 1.131 affidavit cannot be considered unless the applicant is found to be claiming an invention which is patentably distinct from that claimed in the patent. See *In re Clark*, 457 F.2d 1004, 173 USPQ 359 (CCPA 1972) and *In re Hidy*, 303 F.2d 954, 133 USPQ 650 (CCPA 1962)."

Therefore, the counts of interference between the application and patent follow below:

Claim 1 recites,

"1. A microfluidic device, the device comprising: (i) a body structure with a plurality of microscale channels disposed therein, the plurality of microscale channels comprising: (a) a mixing channel; and (b) a separation channel fluidly coupled to the mixing channel, wherein the

mixing channel has a first cross-sectional area and the separation channel has a second cross-sectional area, which first cross-sectional area is larger than the second cross-sectional area; (ii) a pressure source in fluid communication with the mixing channel, which pressure source introduces one or more samples into the mixing channel by applying pressure to the mixing channel; and (iii) an electrokinetic controller in fluid communication with the separation channel, which electrokinetic controller transports the one or more samples into the separation channel by applying a voltage to the separation channel.

In US 6375817 B1 - Referring to Figures 1 and 4, claim 1 recites:

"A sample plug formation device comprising: a housing defining a separation channel comprising a longitudinal axis and an introduction channel which forms a juncture with the separation channel; a pressure control device independently in communication with the separation channel and the introduction channel wherein a first pressure differential applied to the introduction channel transports a sample to the juncture; and a voltage generator in communication with the separation channel, wherein the voltage generator is adapted to apply an electric potential along the longitudinal axis."

The sample plug formation device and the microfluidic device are both equivalent devices used to move fluid through the channels and separate out a plug from the originally injected sample for further separation. The mixing channel claimed in the instant application is the equivalent of the introduction channel (10) of the patented claim. The separation channel claimed in the instant application is the equivalent of the separation channel (12) of the patented claim. The mixing channel moves media using a pressure control device in the instant application and the introduction channel uses a pressure control device to move sample in the patent. The separation channels in the instant application uses an electrokinetic controller and

the separation channel in the patent uses a voltage generator. The voltage generator is used to make the electrokinetic signal used in the channels of the instant application therefore they are also equivalent. The separation channel and the mixing channel intersect at one point in the instant application and the introduction channel and separation channel also intersect (11).

The channel dimensions of the dependent claims in the instant application are stated below:

"2. The microfluidic device of claim 1, wherein the mixing channel has a depth and a width, which depth is between about 5 μm and about 100 μm and which width is between about 5 μm and about 100 μm .

6. The microfluidic device of claim 1, wherein the separation channel has a depth and a width, which depth is between about 1 μm and about 20 μm and which width is between about 1 μm and about 20 μm ."

The channel dimensions for the patent are stated below:

"4. The sample plug formation device of claim 1, wherein the introduction channel and the separation channel independently have a mean diameter within the range of about 0.1 μm to about 1000 μm ."

The broadest interpretation of the diameter of the patented channels encompasses the ranges claimed for the depth and width of the instant application.

Although the claimed apparatus does not specifically state that the cross sectional area of the electrokinetically controlled separation channel is smaller than that of the pressure induced channel, it is depicted in Figure 4 and would have been obvious to one of ordinary skill in the art that the pressure channel would require a larger volume so that extremely high

pressures are not necessary to introduce sample, keeping the operational safety of the apparatus within OSHA standards.

Therefore, the claims of the instant application are anticipated by the patent implicitly and impliedly and would require an affidavit under 37 CFR 1.608(b).

2. In response to the 102(e) arguments regarding Nikiforov, et al. (US 6471841), the examiner has withdrawn the rejection because of the declaration under 27 CFR 1.131.

3. Regarding claims 10-15 as rejected under 35 U.S.C. 103(a) being unpatentable over Taylor as applied to claims 1-9 and 16-24 and further in view of Christel, et al. In view of examiner's response to applicants arguments supra, the rejection under 103(a) is also maintained.

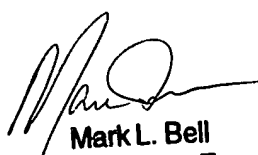
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennine M. Brown whose telephone number is (571) 272-1364. The examiner can normally be reached on M-F 8:00 AM - 6:00 PM; first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Bell can be reached on (571) 272-1362. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 and the examiner's fax number is (571) 273-1364.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1200.

jmb


Mark L. Bell
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Technology Center 1700